UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/821,821	03/29/2001	Andrew A. Welcher	01017/36938A	6210

4743 7590 03/21/2003

MARSHALL, GERSTEIN & BORUN
6300 SEARS TOWER
233 SOUTH WACKER
CHICAGO, IL 60606-6357

EXAMINER
MERTZ, PREMA MARIA

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 03/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/821,821	Applicant(s) Welcher et al.
	Examiner Prema Mertz	Art Unit 1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 21, 2003* .

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1, 4-8, 10, 51-55, 70, and 72* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 4-8, 10, 51-55, 70, and 72* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Claims 2-3, 9, 11-50, 56-69, and 71 have been canceled in Paper No. 9, 1/21/03. Claims 5-7, 55, and amended claims 1, 4, 8, 10, 51-54, 70 (Paper No. 9, 1/21/03), and new claim 72 (Paper No. 9, 1/21/03) are under consideration.

2. Receipt of applicant's arguments and amendments filed in (Paper No. 9, 1/21/03) is acknowledged.

3. The following previous rejections and objections are withdrawn in light of applicants amendments filed in (Paper No. 9, 1/21/03):

(i) the objection to claims 1-8, 10-11, 51-55, 70-71 for reciting non-elected SEQ ID NOS;

(ii) the rejection of claims 1-8, 10-11, 51-55, 70-71 under 35 U.S.C. § 112, first paragraph, for lack of written description;

(iii) the rejection of claims 1-8, 10-11, 51-55, 70-71 under 35 U.S.C. § 112, second paragraph;

(iv) the rejection of claims 1-3 under 35 U.S.C. § 102(b) as being anticipated by Hillier et al. (1997);

(v) the rejection of claims 4-8, 10-11, 51-53 under 35 U.S.C. 103(a) as being unpatentable over Hillier et al (1997).

4. Applicant's arguments filed in Paper No. 9, 1/21/03, have been fully considered and were persuasive in part. The issues remaining are stated below.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 101

6. Claims 5-8, 10, are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

This rejection is maintained for reasons of record set forth at pages 4-5 of the previous Office action (Paper No. 8, 10/15/02).

The rejection of record is maintained over these claims because Applicants have not amended the claims to recite "isolated", to obviate the rejection. Applicants argue that the Patent office has granted numerous patents on subject matter that is used on humans, such as pharmaceuticals and foodstuffs. Applicants arguments are absolutely correct. Numerous patents on subject matter that is used on humans, such as pharmaceuticals and foodstuffs have certainly been granted by the Patent Office. However, Applicants have completely misconstrued the rejection. The issue here is that the instant claims embrace a host cell in the body of a transgenic animal, or a host cell in a gene therapy patient which is non-statutory subject matter under 35 U.S.C. 101.

Claim Rejections - 35 USC § 101

7. Claims 1, 4-8, 10, 51-55, 70, are rejected under 35 U.S.C. § 101.

This rejection is maintained for reasons of record set forth at pages 5-7 of the previous Office action (Paper No. 8, 10/15/02).

Applicants argue that "protein activity" is not the only specific, substantial, and credible utility for the biological molecules claimed and "for example" the polynucleotide of SEQ ID NO:1

can be used as a marker for testicular cells specifically expressing this nucleic acid molecule. However, contrary to Applicants arguments, simply asserting that the instant polynucleotide may be used as a tissue specific probe (page 41, lines 30-32; Example 3, page 112, lines 13-18) is insufficient, because Applicants have failed to demonstrate the differential expression of the claimed polynucleotide as being expressed only in testicular cells and not in any other tissues. According to Applicants disclosure on page 112, lines 15-18, the instant polynucleotide was also detected in human testes, pancreas, a colon adenocarcinoma cell line and an ovarian carcinoma cell line. The employment of a polynucleotide of the instant invention as a tissue specific marker is not a substantial or specific utility since testicular specific proteins were already known in the art. All human proteins can invariably be classified into two categories, those which are expressed in a tissue or developmentally specific manner and those which are expressed ubiquitously. It can be alleged that any protein which is expressed in a tissue specific manner can be employed to detect the tissue in which it is expressed in a sample. Alternately, a human protein which is expressed ubiquitously can be employed to detect the presence of any human tissue in a sample. Such utilities are analogous to the assertion that a particular protein can be employed as a molecular weight marker, which is neither a specific or substantial utility.

Applicants also argue that the claimed polynucleotide of SEQ ID NO:1 is used to map the location of the CD40/IgE receptor-like gene and that SEQ ID NO:1, the related CD20, IgE and HTm_4 genes are clustered within the same region of chromosome 11 (11q 12-13), and that chromosomal aberrations within this region of chromosome 11 are known to be linked to non-

Hodgkin's lymphoma and pathogenesis of various allergic diseases. However, the employment of the nucleic acid, as a probe or as a chromosomal marker is not a substantial or specific utility, because the instant polynucleotides are not diagnostic of a disease and there is no evidence on the record that they are associated with any diseases. Such utilities are analogous to the assertion that a particular DNA can be employed as a molecular weight marker, which is neither a specific or substantial utility. For a review on utility for "Receptors", Applicants are directed to review pages 63-70, Example 12 of the Utility Guidelines on "Receptors".

Applicants argue that the claimed polynucleotide maps to chromosome 11 and therefore the polynucleotide is useful for chromosomal localization, and in particular, the mapping of disease-associated genes located on the chromosome and can be used in genetic linkage analysis. However, the employment of the claimed nucleic acid as a chromosomal marker is not a substantial or specific utility. It can be alleged that all nucleic acid molecules on specific chromosomes can be employed as chromosomal markers of specific chromosomes. Such utilities are analogous to the assertion that a particular protein can be employed as a molecular weight marker, which is neither a specific or substantial utility. Applicants argue that the claimed polynucleotide can be employed in genetic linkage analysis which is commonly used in testing for genetically-inherited diseases and the employment of the claimed nucleic acid in genetic linkage analysis is a credible, specific and substantial utility. However, the employment of the nucleic acid of the instant invention, in genetic-linkage analysis is not a substantial or specific utility. Applicants have not presented evidence that the instant nucleic acid has anything to do with non-

Hodgkin's lymphoma or any allergic diseases or any other disease or condition or that an alteration in this gene has anything to do with any disease or condition.

It can be alleged that any nucleic acid can be employed in genetic linkage analysis. One could just as readily argue that any purified compound having a known structure could be employed as an analytical standard in such processes as nuclear magnetic resonance (NMR), infrared spectroscopy (IR), and mass spectroscopy as well as in polyacrylamide gel electrophoresis (PAGE), high performance liquid chromatography (HPLC) and gas chromatography. None of these processes could be practiced without either calibration standards having known molecular structures or, at least, a range of molecular weight markers having known molecular weights. It was just such applications that the court appeared to be referring to when it expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation (*Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966)). Because the steroid compound which was the subject of that decision had a known structure and molecular weight it could have readily been employed as a molecular standard at that time. However, the court held that the compound at issue did not have a specific and substantial utility.

To grant Applicant a patent encompassing an isolated polynucleotide encoding a naturally occurring human protein of as yet undetermined biological significance would be to grant Applicant a monopoly "the metes and bounds" of which "are not capable of precise delineation". That monopoly "may engross a vast, unknown, and perhaps unknowable area" and "confer power

to block off whole areas of scientific development, without compensating benefit to the public" *Brenner v. Manson, Ibid*). To grant Applicant a patent on the claimed polynucleotide based solely upon an assertion that the polynucleotide can be employed as a chromosomal marker is clearly prohibited by this judicial precedent since the compensation to the public is not commensurate with the monopoly granted.

Applicants are reminded that an invention must be complete as filed. However, based on the specification as filed, there is no disclosure of what the claimed polynucleotide or the protein encoded thereby does or what it can do. There is no practical utility of the claimed polynucleotide in currently available form. Furthermore, no specific disease to be treated, has been enabled by Applicants, using the claimed polynucleotide encoding a protein and neither have Applicants demonstrated the clinical effects of potential agonists or antagonists of the protein. Therefore, the instant invention is not useful in currently available form because the instant polynucleotide has not been used clinically and the use of the instant polynucleotide encoding a protein cannot be foretold with certainty.

The Brenner case has been cited previously for the position that a substantial, specific utility of the claimed protein is required. There is no specific condition disclosed for which the instant product can be used. This requirement is analogous to basic scientific characterization, however, in the instant case no substantial benefit for the polypeptide is currently disclosed, but an exploratory significance. In the absence of a knowledge of the biological significance of the polypeptide, there is no immediately obvious "patentable" use for it. Since the instant

specification does not disclose a "real world" use for the claimed polynucleotide, then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. 101 as being useful. In conclusion, Applicants arguments with respect to utility of the instant polynucleotide, are found to be non-persuasive. Contrary to Applicants arguments, the instant specification does not disclose a single credible, specific or substantial utility for the instant polypeptide.

Claims 1, 4-8, 10, 51-55, 70, also remain rejected under 35 U.S.C. 112, first paragraph, as failing to adequately teach how to use the instant invention. Claims 1, 4-8, 10, 51-55, 70, stand rejected under 35 U.S.C. § 112, first paragraph, because the instant specification does not teach how to use the invention for those reasons of record set forth at pages 7-8 of the previous Office action (Paper No. 8, 10/15/02).

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 305-3014 or (703 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 746-5300.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Prema Mertz

Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
February 10, 2003